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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,368	02/07/2002	Alice C. Martino	C-3527/1/US	2557

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,368

Applicant(s)

MARTINO ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 16-25 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-25 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8-12-2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-9, 16-25, and 32-38 in the reply filed on January 10, 2005 is acknowledged. The traversal is on the ground(s) that both inventions are classified in the same classification and therefore there is no undue burden of search to the Office. This is not found persuasive because even though the inventions are classified in the same classification, the field of search is diverse. See MPEP § 808.02(c). Note that the search field for a composition containing certain ingredients is different from the search field for a particular method of use employing a composition containing the same ingredients. The search field for the methods recited is not coinciding with the search of composition. The search is not limited to the patent files. Therefore, the search for the compositions and methods encompassed by the claims presents an undue burden to the Office. See also the restriction requirement mailed February 12, 2004.

As discussed in the restriction requirement of February 12, 2004, distinctness between the claimed inventions is seen. The method of treating sexual dysfunction can be practiced with a materially different products such as removing the etiology or psychological counseling.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 10, 2005.

Claims 1-9, 16-25, and 32-38 will be examined to the extent they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-7, and 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions "one agent effective ... having molecular weight, excluding counterions, not greater than 250" recited in claim 1, "one agent has a molecular weight, excluding counterions, not greater than 235" recited in claim 2, "one agent has a molecular weight, excluding counterions, not greater than 220" recited in claim 3, "one agent has a solubility in water at 20-25°C of at least about 10g/l" recited in claims 4 and 24 render the claims indefinite because it is not clear what compounds are encompassed by the claims.

The term "having acceptable organoleptic properties" in claims 1 and 23 is a relative term which renders the claim indefinite. The term "acceptable organoleptic properties" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

reasonably apprised of the scope of the invention. Such expression is a relative term that to one some drugs are acceptable but to others, they may not. Due to the individual preference, the metes and bounds of the claims with related to the compounds encompassed thereby would not be ascertained by one of ordinary skill in the art.

The term "causing significant side-effects" in claim 6 is a relative term which renders the claim indefinite. The term "causing significant side-effects" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what would be considered as "significant" and therefore, it is not clear what compounds as encompassed by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-7, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,565,466 ('466).

'466 teaches a buccal composition comprising a vasodilator for modulating the sexual response in human. '466 the buccal dosage form can be formulated into sublingual tablets, lozenge, chewing gums, and oral strips and films (See col. 7, lines

29-49). '466 teaches useful vasodilators include nitroglycerin and nicotiny alcohol(See claim 2).

'466 does not expressly teach a buccal composition containing nicotiny alcohol or nitroglycerin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate either nitroglycerin or nicotiny alcohol into buccal formulation taught in '466 such as sublingual tablets, lozenge, chewing gums, and oral strips and films.

One of ordinary skill in the art would have been motivated to formulate either nitroglycerin or nicotiny alcohol into buccal formulation taught in '466 such as sublingual tablets, lozenge, chewing gums, and oral strips and films since the buccal formulation taught in '466 as useful to deliver the vasodilators such as nicotiny alcohol and nitroglycerin avoiding first-pass metabolism.

Claims 5, 8-9, 23-25 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,565,466 ('466) as applied to claims 1-4, 6-7, 16-21 above and further in view of US Patent 5,273,975 ('975).

'466 teaches a buccal composition comprising a vasodilator for modulating the sexual response in human. '466 the buccal dosage form can be formulated into sublingual tablets, lozenge, chewing gums, and oral strips and films (See col. 7, lines 29-49). '466 teaches useful vasodilators include nitroglycerin and nicotiny alcohol(See claim 2).

'466 does not expressly teach a buccal composition containing compounds recited in claims 5, 8, and 23 and their corresponding amount recited.

'975 teaches the compounds recited in claims 5, 8, and 23 as useful in stimulating sexual activity and treating sexual dysfunction (See col. 2, lines 19-23). '975 also teaches the effective dosage as 10mg orally in multiple doses (See col. 9, lines 58-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate buccal formulations comprising the compounds recited in '975, in the dosage herein claimed.

One of ordinary skill in the art would have been motivated to formulate buccal formulations comprising the compounds recited in '975, in the dosage herein claimed since the compounds of '975 are known to be useful in stimulating sexual response. Therefore, substituting the compounds of '975 for the compounds in '466 to formulate buccal compositions in '466 to stimulate sexual response would have been reasonably expected to be effective.

Claims 1-9, 16, 22-25, 32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over '975 in view of US Patent 5,501,861 ('861).

'975 teaches the compounds recited in claims 5, 8, and 23 as useful in treating anxiety (See the abstract). '975 also teaches the effective dosage as 10mg orally in multiple doses (See col. 9, lines 58-61).

'975 does not expressly teach the compounds as formulated into a fast-melt formulation.

'861 teaches a fast-melt formulation for antianxiety and antidepressants compounds which also provide advantages for providing an easy dosage forms for elderly to ingest (See col. 3, lines 37-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the antianxiety and antidepressant compounds of '975 into fast-melt formulation of '861.

One of ordinary skill in the art would have been motivated to formulate the antianxiety and antidepressant compounds of '975 into fast-melt formulation of '861 since formulate antidepressant and antianxiety compounds of '975 would provide an advantage of fast-melt formulation that is easily ingested for elderly patients. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Primary Examiner
Art Unit 1617